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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/556,658

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Gary Rheinheimer

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SIEMENS CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT
170 WOOD AVENUE SOUTH
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EXAMINER

PAJOOHI, TARA S

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/556,658	Applicant(s) RHEINHEIMER ET AL.	
	Examiner Tara S. Pajoohi	Art Unit 2886	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/18/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. Acknowledgement is made to the amendment filed on 2/18/2008.
2. Claims 1-30 are still pending.

Specification/Drawings

3. The replacement drawings for figures 1-5 and amendments to the specification were received on 2/18/2008. These drawings and amendments to the specification are acceptable.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-6, 21-22 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gross et al. (U.S. Patent # 4,867,946)** in view of **Albarella (U.S. Pub. # 2002/0031840)**.

6. Considering **claims 1, 21 and 28**, Gross discloses (abstract and col. 1-2) and shows in figures 2 and 3, an apparatus and method for verifying proper operation of an optical inspection machine, comprising: a row of colored segments (9) that simulate reagent pads containing types of analytes wherein the row of colored segments are positioned so that segments can be illuminated by the readhead (14) of the optical inspection machine (see fig. 2 and 3).

Gross fails to specifically disclose a row of colored segments that simulate reagent pads containing known types of analytes at known concentrations and comparing the reagents to the reference colored segments by the optical inspection machine.

Albarella discloses (abstract and para. 23) and shows in figures 1 and 15, visually inspecting a test strip with a row of colored segments (12) that simulate reagent pads containing known types of analytes at known concentrations (i.e., reference color areas that represent specific reagents) and visually comparing the

reagents to the reference colored segments but still fails to specifically disclose comparing these results provided by the optical inspection machine.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a reference strip as taught by Albarella in the system of Gross, since Albarella teaches that providing a row or reference colored segments adjacent to the reagent area would allow for easy comparison (para. 7). It would have been further obvious to one having ordinary skill in the art at the time the invention was made to provide the comparison with the optical inspection machine, since it has been held that broadly providing a mechanical or automatic means to replace a manual or visual activity which has accomplished the same result involves only routine skill in the art.

Still lacking the limitation of repeating the steps of determining the results.

It would have been further obvious to one having ordinary skill in the art at the time the invention was made to repeat the steps of determining the results, since it has been held that repeating steps of a method involves only routine skill in the art.

Examiner would also like to point out that the recitation that this apparatus is for verifying proper orientation of an optical inspection machine has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951).

7. Considering **claims 2, 4, 6 and 22**, Gross discloses (col. 1, line 53 – col. 2, line 64) and shows in figure 2, a device for evaluating test strips comprising offset parallel rows of black indicators (5) extending from the rows of colored segments (9), used to properly align the apparatus (i.e., position marks).

8. Regarding **claims 3 and 5**, the modified system of Gross fails to specifically disclose the indicators comprise bosses having flat top surfaces and that the indicators are square.

However, it would have been obvious matter of design choice to change the shape or the indicators such that the indicators have bosses with flat top surfaces or to be square since such a modifications to the

indicators would have involved a mere change in shape and it appears that the invention would perform equally well without such a modification and would be well within the level of ordinary skill in the art. It would have been further obvious in order to provide for easier alignment within the optical inspection machine.

9. Considering **claim 20**, Gross discloses (col. 1, line 53 - col. 2, line 30) the use of different wavelengths to illuminate the test strip.

10. **Claims 7-8, 11-20 and 24-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gross et al. (U.S. Patent # 4,867,946)** in view of **Albarella (U.S. Pub. # 2002/0031840)** and further in view of **Howard (EP Pub. # 0 837 320)**.

11. Considering **claim 7**, the modified system of Gross (para. 23 of Albarella) discloses the row of colored segments (12) are provided on an insert (10) but fails to disclose it is secured to a housing.

Howard discloses (col. 4, lines 8-34) shows in figure 2, the row of colored segments (i.e., absorbent layers of material) are provided on an insert (22) secured to a housing (20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to secure the insert to a housing as taught by Howard in the modified system of Gross, since a housing will provide for more protection to the insert and for a closed environment when doing the optical inspection.

12. Considering **claim 8**, the modified system of Gross fails to specifically disclose the insert is secured within a housing for allowing the insert to be illuminated by the readhead of the optical inspection machine but fails to specifically disclose the housing includes a window.

Howard discloses (col. 4, lines 15-21) and shows in figure 2, the insert (22) is secured within a housing (20) for allowing the insert to be illuminated by the readhead (34) of the optical inspection machine but fails to specifically disclose the housing includes a window.

Therefore, it would have been obvious to one having ordinary skill in the art to provide a window on the housing to allow for the readhead to illuminate the insert through the window since a window would provide closure to the housing that provides for a closed environment for the insert.

13. Considering **claims 11 and 24-27**, the modified system of Gross fails to specially disclose the colored segments include non-white colored segments separated by white segments.

Howard discloses (col. 5, line 44 – col. 6, line 9) and shows in figure 2, the colored segments include non-white colored segments separated by white segments (see figure 2 for non-white colored segments separated by white segments). Howard also discloses the colored segments can be of various colors, including: blue, red, green, black, or white but fails to specifically disclose the specific colors or orange, green, aqua and gray.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the specific colors of orange, green, aqua and gray depending on the analyte to be measured and the wavelength employed by the spectrometer, since it has been held to be within the general skill of a worker in the art to select the color of the material on the basis of its suitability for the intended use as a matter of obvious design choice. Further, it has been held that a recitation with respect to the manner in which a claimed apparatus is indeed to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).

14. Considering **claims 12-14**, the modified system of Gross fails to specifically disclose the colored segments include the colors, orange, green, aqua and gray.

Howard discloses the colored segments can be of various colors, including: blue, red, green, black, or white but fails to specifically disclose the specific colors or orange, green, aqua and gray.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the specific colors of orange, green, aqua and gray depending on the analyte to be measured and the wavelength employed by the spectrometer, since it has been held to be within the general skill of a worker in the art to select the color of the material on the basis of its suitability for the intended use as a matter of obvious design choice. Further, it has been held that a recitation with respect to the manner in which a claimed apparatus is indeed to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).

15. Regarding **claims 15 and 16**, the modified system of Gross fails to specifically disclose the housing of the tray assembly guides the apparatus into the optical inspection machine.

Howard discloses and shows in figures 1 and 2, the housing (20) of a tray assembly (channels 24 and 26) for guiding the apparatus into the optical inspection machine (10), so that the apparatus can be correctly oriented in the tray assembly but fails to specifically disclose orientation features and more specifically different size indents and bosses in order to mate the inspection machine with the housing of the tray assembly.

However as seen in figures 1 and 2, it would be an obvious matter of design choice to provide some type of orientation features to mate the housing of a tray assembly to the optical inspection machine in order to provide for alignment of the system and therefore to provide for accurate measurement and analysis of the inserts.

16. Considering **claim 17**, the modified system of Gross fails to disclose the insert fits in a support tray of the housing of the tray assembly.

Howard shows in figures 1 and 2, an insert (22) to fit in a support tray (24) of the housing of the tray assembly (20) which is used for insertion into the optical inspection machine (10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to secure the insert in a support tray as taught by Howard in the modified system of Gross, since a support tray will provide for more protection and limit the unwanted movement of the insert.

17. Regarding **claims 18 and 19**, the modified system of Gross fails to specifically disclose an opening for the tray assembly and apparatus to be retracted, an inspection location within the opening to receive the apparatus.

Howard shows in figures 1-3, an opening (17, fig 1-2) into which a tray assembly (20) and the apparatus are retracted, an inspection location (see fig. 3) within the opening for receiving the apparatus, a light source (46, fig. 3) for illumination the apparatus when the apparatus is received in the inspection location, and a detector (56, fig. 3) for receiving light reflected off the apparatus from the light source.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an opening to insert the tray assembly and apparatus into the optical inspection machine as taught by Howard in the modified system of Gross, since it provides for a more compact and portable optical inspection machine.

18. Considering **claims 29-30**, the modified method of Gross fails to specifically disclose a top piece for allowing the insert to be illuminated by the readhead of the optical inspection machine and a bottom piece secured to the top piece with the insert secured between the top and bottom pieces, wherein the bottom pieces includes an end wall and side walls extending toward the top piece and that correctly position the insert but fails to specifically disclose the window on the top piece and the bosses extending from opposite ends of the window.

Howard shows in figure 2, a top piece (see fig. 1) for allowing the insert (22) to be illuminated by the readhead (34) of the optical inspection machine (10) and a bottom piece (see fig. 2) secured to the top piece (see side pieces of housing (20) in fig. 2) with the insert (20) secured between the top and bottom pieces, wherein the bottom pieces includes an end wall (see end pieces of housing (20) in fig. 2) and side walls extending toward the top piece and that correctly position the insert but fails to specifically disclose the window on the top piece and the bosses extending from opposite ends of the window.

However it would have been obvious to one having ordinary skill in the art to provide a window on the housing to allow for the readhead to illuminate the insert through the window since a window would provide closure to the housing that provides for a closed environment for the insert. Further, it would be an obvious matter of design choice to provide some type of orientation features (applicants' bosses) in order to provide for proper insertion of the housing into the optical system which would therefore provide for accurate measurement and analysis of the inserts.

19. **Claims 9, 10 and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gross et al.** (U.S. Patent # 4,867,946) in view of **Albarella** (U.S. Pub. # 2002/0031840) and **Howard** (EP Pub. # 0 837 320) and further in view of **Matzinger et al.** (U.S. Patent # 6,168,957).

20. Regarding **claim 9**, the modified system of Gross fails to specifically disclose the insert is made from paper and the colored segments are printed ink.

However in the same field of endeavor, Matzinger discloses (col. 4, lines 38-41) the insert is made from paper.

It would have been obvious to one having ordinary skill in the art at the time the invention was made for the insert to be made of paper, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. It would have been further obvious to use paper as the material of choice for the insert to provide for a less expensive and disposable material for the insert.

21. Considering **claims 10 and 23**, the modified system and method of Gross fails to disclose the colored segments are printed ink.

In the same field of endeavor, Matzinger discloses (col. 6, lines 46-57) the colored segments are applied via ink-jet printing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made for the colored segments to be printed ink, since it is easier to control the appropriate ratio of ink applied (col. 6, lines 46-57).

Response to Arguments

22. Applicant's arguments see pages 11-14, filed 2/18/2008, with respect to the rejection(s) of claim(s) 1-30 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection has been made above and therefore this action is made non-final.

23. Applicant failed to provide any arguments regarding their position on the references used to reject claims 2-6, 8-10, 12-16 and 20-30, specifically Gross and Matzinger references, but only on how the Howard reference failed to teach the limitations of "an apparatus for verifying proper orientation of an optical inspection machine" and "the colored marker fields do not simulate reacted reagent pads at known

concentrations of analyte". Therefore since the applicant appears to agree with the examiners position with respect to the Gross and Matzinger references, the same rational for the previous action was used.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara S. Pajoohi whose telephone number is (571)272-9785. The examiner can normally be reached on Monday - Thursday 9:00 a.m. - 5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tarifur R. Chowdhury can be reached on 571-272-2287. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Tara S. Pajoohi
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